

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US06/30302

A. CLASSIFICATION OF SUBJECT MATTER IPC: A61B 10/06(2006.01) USPC: 600/564 According to International Patent Classification (IPC) or to both national classification and IPC												
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) U.S. : 600/562-567; 606/83, 167, 170, 172, 174, 175, 184, 185, 205, 206 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)												
C. DOCUMENTS CONSIDERED TO BE RELEVANT												
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.										
X ---	US 4,200,111 (HARRIS) 29 April 1980 (29.04.1980) entire document	1-4,6-10, 12, 13 -----										
Y		5,11, 14-19										
X ---	US 6,110,127 (SUZUKI) 29 August 2000 (29.08.2000) entire document	1-4, 6-10, 12, 13 -----										
Y		5, 11, 14-19										
X ---	US 6,142,957 (DIAMOND et al.) 7 November 2000 (07.11.00) entire document	1-4,6-10,12,13 -----										
Y		5,11,14-19										
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.												
* Special categories of cited documents: <table border="0"> <tr> <td>"A" document defining the general state of the art which is not considered to be of particular relevance</td> <td>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>"E" earlier application or patent published on or after the international filing date</td> <td>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>"O" document referring to an oral disclosure, use, exhibition or other means</td> <td>"&" document member of the same patent family</td> </tr> <tr> <td>"P" document published prior to the international filing date but later than the priority date claimed</td> <td></td> </tr> </table>			"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	"E" earlier application or patent published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family	"P" document published prior to the international filing date but later than the priority date claimed	
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Date of the actual completion of the international search 20 June 2008 (20.06.2008)		Date of mailing of the international search report 03 JUL 2008										
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201		Authorized officer Todd Manahan Telephone No. n/a										

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
THADDEUS J. FALESKI
CONLEY ROSE, P.C.
P.O. BOX 3267
HOUSTON, TX 77253-3267

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year)

08 JUL 2008

FOR FURTHER ACTION

See paragraph 2 below

Applicant's or agent's file reference

2329-01202

International application No.

PCT/US06/30302

International filing date (day/month/year)

31 July 2006 (31.07.2006)

Priority date (day/month/year)

29 July 2005 (29.07.2005)

International Patent Classification (IPC) or both national classification and IPC

IPC: **A61B 10/06** (2006.01)

USPC: 600/564

Applicant

X-STEN, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (571) 273-3201

Date of completion of this opinion

20 June 2008 (20.06.2008)

Authorized officer

Todd Manahan

Telephone No. n/a

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Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:
 - a. type of material
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US06/30302

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims 5, 11, 14-19 YES

Claims 1-4, 6-10, 12, 13 NO

Inventive step (IS)

Claims NONE YES

Claims 1-19 NO

Industrial applicability (IA)

Claims 1-19 YES

Claims NONE NO

2. Citations and explanations:

Please See Continuation Sheet

WRITTEN OPINION OF THE
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International application No.
PCT/US06/30302

Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:

Claims 1-4, 6-10, 12 and 13 lack novelty under PCT Article 33(2) as being anticipated by Harris (US 4,200,111).

A tissue excision device comprising: an outer tubular member (15); and an inner tubular member slidably received within the outer tubular member (19,22); wherein the inner tubular member has a distal end including an upper member (27) and a lower member (28); wherein the device has an open position in which the distal end is fully extended from the outer tubular member (Fig. 1), and a closed position (Fig. 4) in which the distal end is disposed within the outer tubular; and wherein the upper member is biased away from the lower member and is disposed at an open angle relative to the lower member when the device is in the opened position. The open angle is between 5 and 30° and between 8° and 20° (at some point when the device is being pushed out of the tubular member it will the angle will fall within this range). The upper member has a fixed end (21) integral with the inner tubular member and a cutting end adapted to cut tissue (37). The upper member is disposed at a closed angle relative to the lower member when the device is in the closed position, wherein closed angle is between 0° and 5° (Fig. 4). The upper member includes a flexing region between the cutting end and the fixed end, wherein the upper member is adapted to flex about the flexing region (Fig. 9). The cutting end of the upper member extends toward the central axis of the inner tubular member at a bent region to form a tooth (31, Fig. 9). The bent region has a curved outer surface. The lower member includes a fixed end (21) integral with the inner tubular member and a cutting end (33) adapted to cut tissue. The lower member is coaxial with the outer tubular member. The outer tubular member includes an annular cutting edge adapted to cut tissue.

Claims 5, 11 and 14-19 lack an inventive step under PCT Article 33(3) as being obvious over Harris (US 4,200,111). Harris does not disclose the length of the upper member. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to change the length of the upper member to fit within the claimed range, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

Harris does not disclose that the cutting end of the lower member has a cutting tip with a beveled edge defined by an acute angle, between 15° and 45°. However it is well known in the art to provide a beveled edge to aid in the function of cutting. It would have been an obvious matter of design choice to a person of ordinary skill in the art to change the angle of the beveled edge to fit within the claimed range, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

Harris does not disclose a plunger slidably received within the inner tubular

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

member. However it is well known in the art to incorporate a plunger for the purposes of removing the specimens that have been retrieved by the device. Therefore adding the feature of a plunger would not be novel.

Harris discloses the steps for using the cutting device as claimed but does not disclose that the method is for treating stenosis in a spine. However, it would have been obvious to adapt the device for retrieving tissue into a method of treating a spine since the need for removing tissue from a spine for treatment of the spine is well known in the art.

Harris does not disclose a kit for performing a procedure on a spine comprising an insertion member for accessing the epidural space and a volume of a contrast medium. However, it is well known in the art to use a trocar or introducing catheter for the purposes of providing easy access to the area of treatment. It is further well known to use contrast medium to simplify the procedure by marking the location of the procedure prior to delivering devices to the area. Therefore it would have been well within the skill of the ordinary artisan to incorporate these elements into a kit for use by a surgeon during one procedure.

Claims 1-19 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.